

§ 20.43

21 CFR Ch. I (4–1–02 Edition)

(2) *Advance payment.* If a requester has failed to pay previous bills in a timely fashion, or if the Food and Drug Administration's initial review of the request indicates that the charges will exceed \$250, the requester will be required to pay past due fees and/or the estimated fees, or a deposit, before the search for the requested records begins. In such cases, the requester will be notified promptly upon receipt of the request, and the administrative time limits prescribed in § 20.41 will begin only after there is an agreement with the requester over payment of fees, or a decision that fee waiver or reduction is appropriate.

(3) *Billing and payment.* Ordinarily, the requester will be required to pay all fees before the Food and Drug Administration will furnish the records. At its discretion, the Food and Drug Administration may send the requester a bill along with or following the records. For example, the Food and Drug Administration may do this if the requester has a history of prompt payment. The Food and Drug Administration may also, at its discretion, aggregate the charges for certain time periods in order to avoid sending numerous small bills to frequent requesters, or to businesses or agents representing requesters. For example, the Food and Drug Administration might send a bill to such a requester once a month. Fees should be paid in accordance with the instructions furnished by the person who responds to the request.

[59 FR 533, Jan. 5, 1994]

§ 20.43 Waiver or reduction of fees.

(a) *Standard.* The Associate Commissioner for Public Affairs will waive or reduce the fees that would otherwise be charged if disclosure of the information meets both of the following tests:

(1) Is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government; and

(2) It is not primarily in the commercial interest of the requester. These two tests are explained in paragraphs (b) and (c) of this section.

(b) *Public interest.* Disclosure of information satisfies the first test only if it furthers the specific public interest of being likely to contribute significantly

to public understanding of Government operations or activities, regardless of any other public interest it may further. In analyzing this question, the Food and Drug Administration will consider the following factors:

(1) Whether the records to be disclosed pertain to the operations or activities of the Federal Government;

(2) Whether disclosure of the records would reveal any meaningful information about Government operations or activities that is not already public knowledge;

(3) Whether disclosure will advance the understanding of the general public as distinguished from a narrow segment of interested persons. Under this factor, the Food and Drug Administration may consider whether the requester is in a position to contribute to public understanding. For example, the Food and Drug Administration may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information to the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence; and

(4) Whether the contribution to public understanding will be a significant one, i.e., will the public's understanding of the Government's operations be substantially greater as a result of the disclosure.

(c) *Not primarily in the requester's commercial interest.* If disclosure passes the test of furthering the specific public interest described in paragraph (b) of this section, the Food and Drug Administration will determine whether disclosure also furthers the requester's commercial interest and, if so, whether this effect outweighs the advancement of that public interest. In applying this second test, the Food and Drug Administration will consider the following factors:

(1) Whether disclosure would further a commercial interest of the requester, or of someone on whose behalf the requester is acting. Commercial interests include interests relating to business,

trade, and profit. Both profit and non-profit-making corporations have commercial interests, as well as individuals, unions, and other associations. The interest of a representative of the news media in using the information for news dissemination purposes will not be considered a commercial interest.

(2) If disclosure would further a commercial interest of the requester, whether that effect outweighs the advancement of the public interest as defined in paragraph (b) of this section.

(d) *Deciding between waiver and reduction.* If the disclosure of the information requested passes both tests described in paragraphs (b) and (c) of this section, the Food and Drug Administration will normally waive fees. However, in some cases the Food and Drug Administration may decide only to reduce the fees. For example, the Food and Drug Administration may do this when disclosure of some but not all of the requested records passes the tests.

(e) *Procedure for requesting a waiver or reduction.* A requester must request a waiver or reduction of fees at the same time as the request for records. The requester should explain why a waiver or reduction is proper under the factors set forth in paragraphs (a) through (d) of this section. Only the Associate Commissioner for Public Affairs may make the decision whether to waive or reduce the fees. If the Food and Drug Administration does not completely grant the request for a waiver or reduction, the denial letter will designate a review official. The requester may appeal the denial to that official. The appeal letter should address reasons for the Associate Commissioner's decision that are set forth in the denial letter.

[59 FR 534, Jan. 5, 1994]

§ 20.44 Presubmission review of request for confidentiality of voluntarily submitted data or information.

(a) Any person who is considering submission of data or information voluntarily to the Food and Drug Administration may forward to the Director of the Center involved, or to the Associate Commissioner for Regulatory Affairs, a request for presubmission review of the records involved to deter-

mine whether the Food and Drug Administration will or will not make part or all of them available for public disclosure upon request if they are submitted. Any such request shall state why the data or information involved fall within an exemption from public disclosure set out in subpart D of this part and shall enclose the records involved.

(b) Pending a determination upon such request, the records involved shall be held confidentially and separately by the Food and Drug Administration and shall not be received as part of Food and Drug Administration files.

(c) Pursuant to such a request, the Food and Drug Administration shall make a determination whether part or all of the records involved will be made available for public disclosure upon request if they are submitted. A determination of confidentiality will be made only if it is concluded that the data or information involved fall within an exemption from public disclosure set out in subpart D of this part and are relevant to and important for agency activity.

(d) After a determination is made pursuant to this section, the Food and Drug Administration shall receive as part of its files the records for which a request for confidentiality has been granted and shall so mark or designate those records. The person requesting the presubmission review shall have the option of submitting or withdrawing the records for which a request for confidentiality has been denied. No copy or summary of records withdrawn pursuant to this section, or any correspondence or memoranda or records relating thereto, shall be retained in Food and Drug Administration files.

(e) A determination of confidentiality pursuant to this section is subject to the limitations established in subpart E of this part except that the data or information involved shall not be subject to discretionary release pursuant to § 20.82. Such a determination of confidentiality by the Food and Drug Administration means that the Food and Drug Administration will not make the data or information involved available for public disclosure unless ordered to do so by a court.